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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,274	12/11/2001	Randolf von Oepen	JM-10 CIP	7012

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LUCE, FORWARD, HAMILTON & SCRIPPS LLP
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EXAMINER

HUGHES, ALICIA R

ART UNIT PAPER NUMBER

1614

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- I. Claims 1-13, drawn to a process of reducing restinosis, classified in class 514, subclass 310.
- II. Claims 14-20, drawn to a product designed to inhibit restenosis in patient vessels, classified in class 514, subclass 310.

Inventions I and II are related as product and process of use. The product of Invention II, a kit containing a moiety, a tubular structure, and a catheter, can be used to reduce restinosis, the process claimed as Invention I.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP §806.05(h). In the instant case the product can be used in materially different processes, for example, the treatment of coronary artery disease, valvular heart disease, congestive heart failure, and/or catheter-based heart repair, from the process claimed in Invention I. Since the product claimed in Invention II can be used in a process that is materially different from the process for reducing restenosis, as claimed in Invention I, restriction is proper.

Rejoinder Notice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election

This application contains claims directed to the following patentably distinct species: a radioactive restenosis-inhibiting moiety and a neutron-capture restenosis-inhibiting moiety. The species are independent or distinct, because a radioactive restenosis-inhibiting moiety can inhibit cell growth and proliferation whereas a neutron-capture restenosis-inhibiting moiety may not.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4-7, 10, 14, 19 and 20 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

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inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Election/Restrictions Proper

MPEP §809.02(d) states, “[w]here only generic claims are presented, no restriction [or election] can be required except in those applications where generic claims recite such a multiplicity of species that an unduly burdensome search is necessary.” Here, the claims recite such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

At the very least, if all claims were examined as presented, the examiner would have the undue burden of performing at least four different independent searches: (1) a method of reducing restenosis utilizing a radioactive moiety; (2) a method of reducing restenosis utilizing a neutron-capture moiety while exposing the stent to a neutron flux; (3) a product including a radioactive moiety; and (4) a product including a neutron-capture moiety. Each search would be capable of producing its own, independent invention.

It is easy enough to understand the variation between a search for a product versus a process. Within these subsets, however, lie yet another search variation – the neutron-capture moiety versus the radioactive moiety. Radioactive moieties respond differently than neutron capture moieties. For example, radioactive moieties are known for their ability to form excited molecules, thereby causing physical damage to cells and DNA. Additionally, radioactive moieties are capable of being traced through the body, precisely revealing a number of biochemical and metabolic processes, thereby aiding disease diagnosis and furthering research in

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a manner distinct from neutron-capture moieties. As a result of these variable functions and properties, a concurrent search of neutron-capture moieties and radioactive moieties create an unduly extensive and burdensome search for the examiner.

In light of the foregoing, the claimed inventions are patently distinct and capable of supporting their own patents. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction and election for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-6026.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

29 September 2006

ARH

 9/30/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER